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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,125	02/21/2006	Andrew Chee-Yuen Chan	146392000401	2225

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
04/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,125	CHAN ET AL.	
	Examiner	Art Unit	
	Q. JANICE LI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10,11,13,16,17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,11,13,16,17,19-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The request for reconsideration of the finality of the prior Office action has been considered and granted. It is an inadvertent error that the first page of the prior Office action was marked as final.

The amendment and remarks submitted on March 28, 2008 are acknowledged and entered. Claims 7, 9, 12, 14, 15, 18 have been canceled. Claims 1-3, 11 have been amended. Claims 1-6, 8, 10, 11, 13, 16, 17, 19-28 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated.

Claim Objections

Claims 24-28 stand objected to under 37 CFR 1.75 as being a substantial duplicate of claims 8, 10, 11, 20, 21, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, both sets of claims are directed to a method where the numbers of B cells or pre-B cells are compared at before and after administering an agent, while the first set of claims set forth explicitly the method steps.

In the remarks, the applicant argues that claims 24-28 have less steps and thus broader scope.

The argument has been fully considered but found not persuasive. This is because the second set of claims rephrases steps of the first set of claims, but both set of claims comprise the same number of steps. For example, claim 24 recites, "*comparing the number of B lymphocytes and/or pre-B cells expressing human CD20 in a mouse of claim 1 after administering an agent to the mouse to the number of B lymphocytes and/or pre-B cells expressing human CD20 in the mouse before administration of the agent*" (emphasis added). Thus, although not explicitly counted, three steps have to be involved in claim 24, i.e. a) measuring the number of B lymphocytes before administration; b) administering a agent; c) measuring the number of B cells/pre-B cells after administration, so that the numbers could be compared. Hence, the two sets of claims have the same steps and scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 10, 11, 13, 16, 17, 19-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Wadsworth et al.* (USP 5,720,936), in view of *Countouriotis et al.* (Stem Cells 2002:20:215-229), and *Capecchi et al.* (US 5,627,059), for reasons of record and following.

In the remarks, the applicant argues that the amended claims recite human CD20 is expressed on the surface of B lymphocytes and none of the cited art teaches expressing CD20 on the surface of B cells.

The argument has been fully considered but found not persuasive because CD20 is naturally expressed on the surface of B cells. By employing the CD20 promoter, and relying on genetically built-in mechanism, the CD20 would be expressed on the surface of B/pre-B cells. *Wadsworth et al.* teaches using the APP promoter to express human APP gene, indicating it was known in the art to use the endogenous promoter of the gene to express a gene. It would have been obvious to the skilled to use a human CD20 promoter to express a human CD20 gene.

The applicant then argues the art of transgenic animal is unpredictable.

In response, at the time of instant effective filing date, techniques for making transgenic mouse have become routine in the art in view of the teaching of *Capecchi et al* and the state of the art as a whole. Hence making hCD20 transgenic mouse may require some effort, but the effort falls within the bounds of routine experimentation.

Accordingly, in the absence of evidence to the contrary, the rejection stands.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI/
Primary Examiner,
Art Unit 1633

QJL
April 23, 2008